A/RE

Practitioner's Docket No. 498-18 DIV/RES **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Date: 8/5/99

Assistant Commissioner for Patents
Washington, D.C. 20231

REISSUE APPLICATION TRANSMITTAL

Transmitted herewith is the application for reissue of U.S.

☒ Utility Patent ☐ Plant Patent ☐ Design Patent

No. 5,653,746 issued on August 5, 1997

Inventor(s): Schmitt, Peter J.

Title: Radially Expandable Tubular Prosthesis

Enclosed are the following:

1. Specification, claim(s) and drawing(s) (37 C.F.R. § 1.173)

(a) ☒ 8 page(s) of specification

☒ 4 page(s) of claims

☒ 1 page(s) of abstract

NOTE: This must include the entire specification and claims of the patent, with the matter to be omitted by reissue enclosed in square brackets. Any additions made by the reissue must be underlined, so that the old and new specifications and claims may be readily compared. Claims should not be renumbered. The numbering of claims added by reissue should follow the number of the highest numbered patent claim. No new matter shall be introduced into the specification. (37 C.F.R. § 1.173).

CERTIFICATION UNDER 37 C.F.R. § 1.10*
(Express Mail label number is mandatory.)
(Express Mail certification is optional.)

I hereby certify that this Reissue Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date August 5, 1999, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EJ279941065US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Jennifer Bruns
(type or print name of person mailing paper)

Jennifer Bruns
Signature of person mailing paper

WARNING: *Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. § 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.*

***WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).*
*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

(b) ☒ 5 sheet(s) of drawing (drawings amended)

☐ Formal

☒ Informal

NOTE: "Amendments which can be made in a reissue drawing, that is, changes from the drawing of the patent, are restricted." 37 C.F.R. § 1.174(b).

☒ No changes in the drawings, upon which the original patent was issued, are to be made. Therefore, in accordance with 37 C.F.R. § 1.174(a), please find attached, in the size required for original drawings:

☐ a copy of the printed drawings of the patent.

☐ a photoprint of the original drawings.

☒ A letter requesting transfer of the drawings from the original patent file to this reissue application is attached.

2. Declaration and power of attorney

☒ 6 pages of declaration and power of attorney

3. Preliminary amendment

(check, if applicable)

☐ Attached

4. Offer to surrender the original letters patent in accordance with 37 C.F.R. § 1.178 is attached.

☒ Offer to surrender is by the inventor

☒ along with assent of assignee.

☐ Offer to surrender is by the assignee of the entire interest (and the reissue application does not seek to enlarge the claims of the original patent).

5. Letters patent

☒ Original letters patent are attached.

☐ Declaration that original letters patent lost or inaccessible is attached.

☐ A copy of the original printed patent is attached.

NOTE: "The application may be accepted for examination in the absence of the original patent or the declaration but one or the other must be supplied before the case is allowed." 37 C.F.R. § 1.178.

NOTE: "Where the original patent grant is not submitted with the reissue application as filed, patentee should include a copy of the printed original patent. Presence of a copy of the original patent is useful for the calculation of the reissue filing fee and for the verification of other identifying data." M.P.E.P., § 1416, 7th ed.

NOTE: "If a reissue be refused, the original patent will be returned to applicant upon his request." 37 C.F.R. § 1.178.

6. Petition to proceed without assignee's assent

☐ Attached hereto is a "PETITION TO PROCEED WITH REISSUE APPLICATION WITHOUT ASSIGNEE'S ASSENT".

A. ☐ The fee payment is authorized in the attached:

☐ "REISSUE APPLICATION TRANSMITTAL" Form

☐ "COMPLETION OF FILING REQUIREMENTS — REISSUE APPLICATION" Form.

B. ☐ Payment is authorized below.

7. Information Disclosure Statement

☐ Attached

☐ Copies of the IDS citation(s) is/are attached.

8. Priority—35 U.S.C. § 119

☐ Priority of application Application No. 0 / _____, filed on _____, in _____ is claimed under 35 U.S.C. § 119.
Country

☐ The certified copy has been filed in prior application Application No. 0 / _____ filed on _____.

9. Basic Filing Fee Calculation (37 C.F.R. § 1.16(h), (i) and (j))

CLAIMS AS FILED					
Number Filed		Number Extra		Rate	Basic Fee (37 C.F.R. 1.16(h)) $760.00
Total Claims (37 C.F.R. § 1.16(j))	21	– 20 *(and also in excess of total claims in patent)*	X	$18.00	18.00
Independent Claims 37 C.F.R. § 1.16(i))	6	*–(number of independent claims in patent)*	X	$78.00	468.00
		Filing fee Calculation			$ 1,246.00

NOTE: Multiple dependent claims are treated as ordinary claims for fee purposes. 37 C.F.R. § 1.16(j).

10. Small Entity Status *(if applicable)*

NOTE: A new statement is required for the reissue, even if one has been filed in the original patent. 37 C.F.R. § 1.27(a).

WARNING: *"Small entity status must not be established when the person or persons signing the . . . statement can **unequivocally** make the required self-certification." M.P.E.P. § 509.03, 6th ed., rev. 2, July 1996 (emphasis added).*

☐ A statement that this filing is by a small entity is

☐ attached.

Filing Fee Calculation (50% of above) $_____

NOTE: If a statement is filed within 2 months of the date of timely payment of a fee, then the excess fee paid will be refunded on request. 37 C.F.R. § 1.28(a). Effective April 1, 1984.

11. Additional Fee Payments

☐ Payment is being made for "PETITION TO PROCEED WITH REISSUE APPLICATION WITHOUT ASSIGNEE"
(37 C.F.R. § 1.17(h)) $130.00

12. Total Fees Due

Filing Fee		$1,246.00
Petition fee		$_____
	Total Fees Due	$_____

13. Method Of Payment of Fees

☒ Enclosed is a check in the amount of $1,246.00.

☐ Charge Account No. _____ in the amount of $_____.
A duplicate of this request is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. § 1.22(b).

14. Authorization To Charge Additional Fees

WARNING: *If no fees are to be paid on filing, the following items should not be completed.*

WARNING: *Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.*

☒ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. 08-2461 :

☒ 37 C.F.R. § 1.16(a), (f) or (g) (filing fees)

☒ 37 C.F.R. § 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

☒ 37 C.F.R. § 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

☒ 37 C.F.R. § 1.17(a)(1)–(5) (extension fees pursuant to § 1.136(a)).

☒ 37 C.F.R. § 1.17 (application processing fees)

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

NOTE: "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

NOTE: See 37 C.F.R. § 1.28.

15. ☐ **Additional Enclosures**

AUG. 5, 1999

Reg. No.: 30,152

Tel. No.: (973) 331-1700

Customer No.:

SIGNATURE OF PRACTITIONER

Salvatore J. Abbruzzese
(type or print name of practitioner)

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Syosset, New York 11791

ASSENT OF ASSIGNEE TO REISSUE

The undersigned, assignee of the entire interest in the above-mentioned letters patent, hereby assents to the accompanying application.

STATEMENT BY ASSIGNEE

☒ Attached is a "STATEMENT UNDER 37 C.F.R. 3.73(b)," establishing the right of the assignee to take action in this reissue.

Date: Aug 4, 1999

Signature of assignee;
(type or print name of signatory and title if signing on behalf of an entity)

David L. Cavanaugh
Senior Patent Counsel

LIMITED AUTHORIZATION TO ACT ON BEHALF OF ASSIGNEE REGARDING CERTAIN PATENT MATTERS EFFECTIVE THROUGH: December 31, 1999

****

I, Paul W. Sandman, as Senior Vice President, Secretary, and General Counsel of Boston Scientific Corporation, the controlling corporation of:

Scimed Life Systems, Inc., Boston Scientific Corporation Northwest Technology Center, Inc.; Symbiosis Corporation; Meadox Medicals, Inc.; E.P. Technologies, Inc.; Cardiovascular Imaging Systems, Inc.; BSC Technology, Inc.; Boston Scientific Technology, Inc.; Scimed Technology, Inc.; Meadox Technology, Inc.; Boston Scientific, Limited; Boston Scientific Ireland, Limited; Corvita Corporation; Cardiovascular Innovations Canada, Inc.; Corvita Europe S.A; Corvita Canada, Inc.; Laboratoires Corvita S.A.R.L.; Schneider (Europe) GmbH; Nilo Holding, S.A.; AMS Medinvent S.A.; Schneider Belgium NV; Schneider Holland BV; Schneider (USA), Inc.; Schneider/NAMIC; Schneider Puerto Rico; NAMIC Eireann Limited; NAMIC International, Inc.; Schneider Ireland BV; and Target Therapeutics, Inc.,

hereby authorize the following registered patent attorneys/agents (1) to act on behalf of any of the corporations identified above, including Boston Scientific Corporation, with regard to any matters before the United States Patent and Trademark Office, any foreign patent offices, and any international patent entities, (2) to execute power of attorney documents on behalf of any of the corporations identified above, including Boston Scientific Corporation, to appoint and/or establish any attorneys, agents, and/or law firms to act on behalf of any of the corporations identified above, including Boston Scientific Corporation, in any foreign or international patent applications filed with any foreign and/or international patent offices, and (3) to execute assignment and ownership documents on behalf of any of the corporations identified above, including Boston Scientific Corporation, with regard to any matters before the United States Patent and Trademark Office, any foreign patent offices, and any international patent offices:

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Paul W. Sandman
Senior Vice President, Secretary, and General Counsel

Jan. 6, 1999
Date

COMMONWEALTH OF MASSACHUSETTS)
) ss.
COUNTY OF MIDDLESEX)

On this 6th day of January, 1999 before me personally appeared Paul W. Sandman to me known and known to me to be the person described in and who executed the foregoing instrument, and he duly acknowledged to me that he executed the same for the uses and purposes set forth herein.

Notary Public

NONA E. HURD
NOTARY PUBLIC
My Commission Expires Oct. 4, 2002

:680a

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Peter J. Schmitt

Patent No.: **5,653,746** (Serial No.: 08/462,230)

Issued: **August 5, 1997** (Filed: June 5, 1995)

For: RADIALLY EXPANDABLE TUBULAR PROSTHESIS

Docket: 498-18 DIV/RES

Date 8/5/99 Label No. EJ27994165US
I hereby certify that on the date indicated above I deposited this paper or fee with the U.S. Postal Service and that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, D.C. 20231 by "EXPRESS MAIL Post Office to Addressee" service.
Signature [signature] JenniferBruns

Assistant Commissioner for Patents
Washington, DC 20231

STATEMENT UNDER 37 C.F.R. §3.73(b)

Meadox Medicals, Inc., states that it is the assignee of the entire right, title, and interest in the above-identified patent application, by virtue of an assignment from the inventors of the application identified above. The assignment was recorded in the U.S. Patent and Trademark Office on January 14, 1993 at Reel 6397/Frames 0432-0435. It is respectfully noted that Boston Scientific Corporation, a Delaware corporation is the controlling corporation of Meadox Medicals, Inc.

The undersigned is empowered to sign this statement on behalf of the assignee, as evidenced by the attached authorization form.

Respectfully submitted,

[signature]
David L. Cavanaugh
Senior Patent Counsel
Registration No.: 36,476

Date: Aug. 4, 1999

HOFFMANN & BARON, LLP
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RADIALLY EXPANDABLE TUBULAR PROSTHESIS

This is a divisional of application(s) Ser. No. 08/208,182 filed on Mar. 8, 1994, now U.S. Pat. No. 5,443,499.

BACKGROUND OF THE INVENTION

The present invention relates to a tubular prosthesis and, more particularly, to a radially expandable tubular prosthesis which allows controlled expansion in a circumferential direction following implantation while limiting expansion in a longitudinal direction.

The typical prosthesis of the prior art is manufactured with a predetermined diameter, that is, prostheses are manufactured in various sizes so that the physician may choose the most appropriate-sized prosthesis to replace or repair the damaged lumen in the patient. As far as length is concerned, the physician merely cuts the chosen prosthesis to size, the prosthesis typically being oversized in the longitudinal direction.

The commonly-employed prosthesis mentioned above is suitable for use in many situations. However, several applications may demand that the prosthesis be expandable in the radial direction. For example, one such application involves intraluminal implant procedures in which the prosthesis is delivered to a damaged lumen via a catheter. The technique requires that the implant be stored within the catheter (e.g., it may be rolled or bunched) prior to insertion of the catheter into the patient. Upon advancement of the catheter to the site of the damage, the implant is expelled from the catheter, unrolled (or unfolded) and thereafter secured to the lumen. Because of the procedure, it is difficult, if not impossible, for the physician to correct any mismatch in sizing that may occur between the implant and the host lumen. For example, if the physician miscalculates the size of the lumen receiving the implant or should the lumen prove to be larger or smaller than anticipated by the physician, the physician may not be able to securely fix the implant to the host lumen.

Another application in which it would be desirable to employ an expandable prosthesis involves the area of pediatrics. A common disadvantage encountered in conventional pediatric prostheses is the inability of the device to accommodate growth changes in the surrounding tissue as the child ages. Consequently, it is often necessary to perform several surgical procedures on a child to implant ever increasingly circumferentially-larger prostheses. It has traditionally been necessary to entirely remove and replace the implanted prosthesis with a larger-sized prosthesis as the child grows. Such a series of surgeries is traumatic to the body and has a degree of risk inherently associated therewith.

Accordingly, it would be desirable to provide a tubular prosthesis which allows for circumferential expansion such that the prosthesis could be readily deployed via a catheter for intraluminal delivery and, further, such that the prosthesis could be circumferentially expanded in vivo as the child grows, thereby eliminating the need, or at least the frequency, for surgical replacement of the implant.

SUMMARY OF THE INVENTION

The present invention, which addresses the needs of the prior art, provides a radially expandable tubular prosthesis. Any type of textile pattern may be used in manufacturing the prosthesis provided its structure will allow for use of undrawn or partially drawn yarns which will provide circumferential expansion, the primary purpose being the ability to be drawn in vivo subsequent to implantation, e.g., via

balloon catheter or the like. For example, woven, knitted, braided and filament wound fabrics may be used. Thus, in one embodiment, the prosthesis is made from a polymeric fabric having a sufficient portion of yarn which is capable of being drawn beyond the yield point of plastic deformation upon the application of force thereto sufficient to exceed the yield point to allow for radial expansion of the prosthesis.

The prosthesis of the present invention may be used in a wide variety of applications. For example, the prosthesis may be employed as a graft in the vascular system, as well as the esophageal, stomach and bowel areas. Alternatively, the prosthesis may be intraluminally implanted via a catheter or similar device to repair or support a weakened or damaged lumen, such as a blood vessel in the vascular system.

In one preferred embodiment, the prosthesis is made from a woven fabric having substantially drawn longitudinal yarns (warp yarns) which limit expansion or elongation of the prosthesis in the longitudinal direction, and radial yarns (fill yarns) which are at most partially drawn to allow for expansion of the prosthesis in the radial direction when the yield point of he radial yarns is exceeded.

The present invention also provides a method for intraluminally repairing a damaged lumen with an expandable prosthesis via a catheter. The method includes the step of introducing the catheter intraluminally to the damaged lumen. The method also includes the step of delivering the prosthesis intraluminally at the site of damage in the lumen. The method includes the further step of expanding the prosthesis circumferentially until its diameter substantially conforms to that of the damaged lumen.

Due to its unique features, delivery of prostheses to damaged vessels can be accomplished using less invasive methods than conventional implant surgery and with more ease and less uncertainty than conventional methods requiring coiling or folding of the device during delivery via a catheter. The prostheses of the present invention can be delivered intraluminally via a catheter without the need for conventional bunching, folding or rolling of the prosthesis for stowage in the catheter. Instead, the catheter is initially formed with a sufficiently small diameter that allows the prosthesis to be stowed on the catheter without rolling or bunching, delivered to the site of deployment, expanded to the proper size and deployed. Because the prosthesis is not rolled or bunched, the delivery process is more readily accomplished and, in addition, the prosthesis may be more easily maneuvered inside the lumen. (However, depending upon the degree of expandability, the graft may still need to be bunched or rolled, but to a lesser degree than a non-expandable graft.) Further, the prosthesis of the present invention may be implanted in a child, and, thereafter, expanded via a balloon catheter to enlarge the diameter of the implanted prosthesis to substantially conform with the enlarged diameter (due to growth) of the host lumen.

The present invention also provides a method for reducing the frequency of surgical replacement of a previously implanted prosthesis in a child. The method includes the step of implanting an expandable prosthesis in a child. The method includes the additional step of delivering internal force to the prosthesis following a period of growth in the child sufficient to expand the prosthesis in a circumferential direction until the diameter of the prosthesis substantially conforms to that of a connecting host lumen which has experienced a period of circumferential growth following a period of growth in the child. The method includes the further step of expanding the prosthesis in a circumferential direction until the diameter of the prosthesis substantially

conforms to the diameter of a connecting host blood vessel which has experienced a period of circumferential growth.

It is apparent from the above discussion that the present invention overcomes important disadvantages of the prior art and satisfies a strong need in the medical industry.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a woven tubular prosthesis;

FIG. **2** is a schematic of a traditional weave pattern;

FIG. **3** is a graph illustrating the stress vs. length relationship for a typical synthetic yarn having been drawn through the yield point of plastic deformation (S_o);

FIG. **4** is an illustration of an implanted tubular prosthesis;

FIG. **5** is an illustration similar to FIG. **4** following a period of growth in the host lumen;

FIG. **6** is a perspective view of a braided tubular prosthesis;

FIG. **6***a* is a schematic of a diamond braid;

FIG. **6***b* is a schematic of a regular braid;

FIG. **6***c* is a schematic of a hercules braid;

FIG. **7** is a perspective view of a knitted tubular prosthesis;

FIG. **7***a* is an enlarged detail of FIG. **7**:

FIG. **8** is a perspective view of a filament wound tubular prosthesis; and

FIG. **8***a* is an enlarged detail of FIG. **8**.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings and, in particular to FIGS. **1–2**, a woven tubular prosthesis **10** is shown. The weave pattern includes warp yarns **12** running along the longitudinal length L of the woven product and fill yarns **14** running around the circumference C of the product.

As is well-known to those skilled in the art, the yarns used in a woven product are typically treated and processed prior to weaving. This treatment commonly includes the step of "drawing" the yarns, i.e., longitudinally stretching the yarns beyond their yield point until complete plastic deformation is accomplished.

Referring to FIG. **3**, the force required to "draw" a yarn increases until the yield point is reached, at which point, the yarn enters a region of plastic deformation (i.e., a region in which the yarn now exhibits loss of its elasticity and ability to change appreciably in length). Once the deformation point in a yarn has been reached through stretching, the material has substantially lost its elastic memory and is more or less "fixed," neither being able to be further stretched or to return to its original length. Yarns which have experienced full deformation through the drawing process are typically used in prostheses because they are ideal for maintaining constant pressures without concern for undesirable stretching or bulging during use. Consequently, these prostheses are by necessity of fixed diameter.

As mentioned above, the present invention utilizes yarns, in the circumferential direction of the tubular prostheses, which have not been drawn or only partially drawn, allowing for future radial expansion through in vivo drawing, i.e., stretching, beyond the yield point, at which time the tubular prosthesis remains fixed at the increased diameter. This type of stretching causes the yarn to undergo inelastic strain, commonly referred to as plastic deformation, whereby the

polymer molecules become newly aligned. The yarn may also be stretched until a point at which the material fractures (the fracture point). The process of drawing the yarn (to a point prior to the fracture point), increases the tensile strength of the yarn and decreases the elongation to failure.

With respect to prior art prosthesis, both of these characteristics (namely, increased tensile strength and decreased elongation) are desirable in that the prior art devices are typically produced to precise diameters in order to approximately match the size of the damaged lumen being repaired. However, several situations exist in which it would be desirable to be able to implant a prosthesis of a relatively small diameter and, thereafter, expand the prosthesis while such prosthesis remains positioned in the patient's body.

As mentioned above, the first application of what may be referred to as an expandable prosthesis concerns intraluminal implantation. In this application, the present invention functions as an endoprosthetic device, i.e., it is employed to internally repair or support a weakened or damaged lumen, e.g., a blood vessel in the vascular system. More particularly, a tubular prosthesis may be implanted in the body by delivering such prosthesis to the damaged lumen via a catheter. Delivering the prosthesis in such a manner greatly reduces the invasiveness of the procedure. For example, assuming a blood vessel positioned in the thorax is damaged, the typical prior art technique would require opening of the chest and rib cage to allow access to the damaged vessel. In contrast, intraluminal implantation eliminates the need, in many situations, for the surgeon to perform highly invasive procedures on the patient. Instead of accessing the lumen at the point of damage, the physician accesses a lumen leading to the damaged site, e.g., the femoral artery in the groin region when an artery in the vascular system requires repair.

Presently, the prostheses being intraluminally implanted are substantially the same prostheses that are implanted invasively. It has been discovered however, that if a prosthesis is woven with undrawn or partially drawn radial yarns, the prosthesis will be capable of circumferential expansion following manufacture of the product. More particularly, if a balloon catheter (or similar device) is inserted into such a prosthesis and is thereafter expanded, the prosthesis will circumferentially expand a slight degree until the yield point is reached. At that point, the radial yarns, i.e., fill yarns, which were not drawn, will plasticly deform, thereby allowing substantial circumferential expansion. The fill yarns, once expanded, will retain their expanded circumferential length. In addition, as mentioned above, the expanded yarns will generally exhibit a greater tensile strength than before.

To secure the prosthesis to the host lumen, a stent may be incorporated into the prosthesis. In that way, both the prosthesis and the stent can be simultaneously and controllably expanded to the desired diameter or until the prosthesis substantially conforms to the diameter of the host lumen. Any suitable means of attaching the stent to the expandable prosthesis, such as hooks, catches, sutures or other similar means may be used. Additionally, the stent may include similar means capable of anchoring the prosthesis in place in the host lumen.

As also mentioned above, the expandable prostheses of the present invention can be used as pediatric implants. More particularly, implanting prostheses in children can prove quite challenging because as children grow, the lumens, e.g., blood vessels, in their bodies also grow (both longitudinally and circumferentially). FIG. **4** illustrates an implant **16** in a blood vessel **18** of a child. At the time of

implantation, the vessel is matched to the site of the connecting host vessels. However, as the child grows, the host vessels grow circumferentially, while the implant remains the same size.

Referring to FIG. 5, this period of growth in the child results in the formation of a "bottleneck" effect in the blood vessel. In other words, the blood must pass from a vessel having a diameter D_1, to a vessel having a reduced diameter D_2 and then to a vessel again having a diameter D_1. This obstruction in the vessel creates a stenosis, which, in turn, reduces blood flow to distal vessels. Further, increased pressure at the junction of the host vessel and graft can be problematic, if not fatal. Insufficient blood supply distal to the stenosis can also cause fatigue and diminished activity levels.

To reduce the risks associated with this phenomenon, physicians routinely remove and replace vascular grafts that have been implanted in children. In turn, a larger-sized graft is implanted in the child, which after a period of growth, will itself have to be removed and replaced. Overall, it may be necessary to perform a large number of surgical procedures on a child requiring a vascular graft, particularly if the child is an infant (during which time rapid growth occurs). As may well be imagined, performing frequent surgical procedures on a child can severely weaken the child, both physically and psychologically.

The expandable prosthesis of the present invention therefore provides a means for reducing (or eliminating) the frequency at which surgical replacement of an implanted graft is necessary. More particularly, an expandable prosthesis is first surgically implanted in a child. After a period of growth in the child, a procedure is performed whereby internal force is delivered to the prosthesis sufficient to expand the prosthesis in a circumferential direction until the diameter of the prosthesis substantially conforms to that of a connecting host lumen which has experienced a period of circumferential growth. This procedure may be accomplished by, for example, a catheterization procedure whereby a balloon catheter is advanced to the site of the graft. The balloon catheter is thereafter inflated until the yield point of the radial fill yarns is exceeded and the graft begins to expand. The graft may then be circumferentially expanded until its diameter is made substantially equivalent to the diameter of the host vessel.

In both of the describe applications, sufficient undrawn or partially drawn yarns must be present in the circumferential direction such that the yield strength would be well in excess of physiological pressure. Thus, the chosen yarn must be sufficiently strong in the radial direction of the graft in the undrawn state to resist harmful fluxuations in diameter or bulging in the unexpanded state. A minimum pressure ratio of about 10:1 yield strength to physiological pressure would suffice. For example, physiologic pressure for hypertensive patients is typically in the 2–4 psi range. This means that the hoop yield strength of the prosthesis should preferably be at least 40 psi to ensure no occurrence of premature expansion. Thus, to induce expansion of the prosthesis, a pressure of at least 40 psi would be required to be introduced. As mentioned above, while it is preferred that expansion be accomplished by balloon catheter, other means suitable to the application may be used.

Although the above discussion has been directed to weaves (i.e., woven products), the same result can be accomplished with braided prosthesis (see FIGS. **6** and **6***a*–**6***c*), knitted grafts (see FIGS. **7** and **7***a*) and filament wound prosthesis (see FIGS. **8** and **8***a*). As further discussed

in the following examples, each of these prostheses can be manufactured to allow circumferential expansion following implantation.

The yarns in the present invention may be selected from a wide variety of synthetic polymers. Among the useful classes of materials are polyesters, polypropylene, polyurethane, polyamide, and copolymers thereof. Those yarns which are chosen for the undrawn, expandable portion of the prosthesis must be capable of withstanding physiological pressures in the undrawn state. In essence, these yarns must in the undrawn state resist any appreciable expansion or distortion under conditions of pressure and stress encountered in the body until such time as expansion is necessary. Expansion pressures will vary depending for the most part on the physical characteristics of the chosen material, but will by necessity exceed the yield point to reach the plastic deformation state at which time the material will remain in the expanded state. As previously stated, for safety reasons, the yield point of the material should preferably exceed the inherent physiological pressures of the host lumen by a factor of at least about ten. Thus, the force required to expand the circumference of the prosthesis is sufficiently high to resist change and remain in the undrawn state until manually expanded via catheter or similar device.

In the manufacture of the prostheses of the present invention, both drawn yarns as well as undrawn or partially drawn yarns are employed. The undrawn or partially drawn yarns are incorporated into the chosen textile pattern in the direction which upon drawing will result in a larger diameter of the device. In the case of woven patterns, the undrawn materials make up the fill yarns. In the case of knitted construction, such as weft knits, or braided patterns such as two dimensional, multiply or three dimensional braids, the undrawn yarns may comprise part of or all of the fabric. The same applies to grafts made from filament winding construction.

As a result of drawing, the polymeric yarns become directionally aligned or oriented. Drawing is generally accomplished at elevated temperatures, although alternatively cold drawing at high speeds is possible. As the polymer cools and recrystallizes, the elongated molecular chains become arranged in a new order which gives a higher modulus and increased stiffness to the yarn. The result is a loss of elongation with a higher strength:strain ratio.

EXAMPLES

Example 1

Woven Construction

The following specifications are used to fabricate a woven prosthesis of the present invention.

Weave—1/1 Plain, Tubular

Warp Yarn—Textured 50 denier/48 filaments polyester fully oriented (drawn)

Fill Yarn—Flat 115 denier/100 filament partially oriented (partially drawn) polyester

Ends per inch—160

Picks per inch—120

Subsequent to weaving the prosthesis, the fabric is scoured in a basic solution of warm water (e.g., 120° F.) and detergent, followed by rinsing to remove the detergent. The prosthesis can then be attached to a stent fixation device and assembled into a catheter delivery system, or, alternatively surgically implanted. Thus the expandable prosthesis can then be delivered intraluminally or be implanted percutaneously.

The partially-oriented fill yarn chosen in this example has the ability to stretch about 1.7 times its original length. Thus, if the woven graft were manufactured to a diameter of 10 mm. dilation with a balloon catheter to about 17 mm can be achieved.

Example 2

Braided Construction

The following specifications are used to fabricate a braided prosthesis of the present invention:

Braid—Regular Twill Braid, Tubular

Yarn—2 ply/flat 115 denier/100 filament partially oriented (partially drawn) polyester

Carriers—96

Helix Angle—55°

Diameter—10 mm

Subsequent to braiding of the prosthesis (see FIGS. **6** and **6***a*–**6***c*), the fabric is scoured in a basic solution of warm water (e.g., 120° F.) and detergent, followed by rinsing to remove the detergent. The prosthesis can then be attached to a stent fixation device and assembled into a catheter delivery system or, alternatively surgically implanted. Thus, the expandable prosthesis can then be intraluminally delivered or implanted percutaneously.

The partially-oriented fill yarn chosen in this example also has the ability to stretch about 1.7 times its original length. Thus, a braided prosthesis manufactured to a diameter of 10 mm would be capable of expanding to about 17 mm in diameter.

Example 3

Weft Knitted Construction

The following specifications are used to fabricate a knitted prosthesis of the present invention:

Knit—Tubular Jersey Weft Knit

Yarn—3 ply/flat 115 denier/100 filament partially oriented (partially drawn) polyester

Wales per inch—30

Courses per inch—40

After knitting (see FIGS. **7** and **7***a*), the fabric is scoured in a basic solution of warm water (e.g., 120° F.) and detergent. It would be rinsed to remove the cleaning agents. The prosthesis can then be attached to a stent fixation device and assembled into a catheter delivery system for insertion into the body or, alternatively directly implanted.

The partially-oriented fill yarn has the ability to stretch about 1.7 times its original length. The knitted fabric geometry provides an additional amount of stretch of about 50% to the overall dilation of the graft. Knitted prostheses manufactured to a diameter of about 10 mm are capable of being dilated with a balloon catheter to about 22 mm.

A warp knit construction can also be used. For example, instead of a tubular jersey weft knit construction, a tubular double tricot warp knit construction with similar stitch density can be used.

Example 4

Filament Wound Construction

A one ply/flat 115 denier/100 filament partially oriented polyester yarn is filament wound onto a mandrel of known

diameter. The helix angle achieved is about 55°. The mandrel is wrapped with the yarn in both directions to provide biaxial reinforcement. To hold the yarns in place. they are passed through a solution of solvated polyurethane elastomer. such as Biomer® solution. sold by Johnson & Johnson. The solvent is removed. causing the polyurethane to dry and glue the yarns together. After filament winding (see FIGS. 8 and 8*a*). the material is scoured in a basic solution of warm water (e.g.. 120° F.) and detergent. followed by rinsing to remove the detergent. The prosthesis can then be attached to a stent fixation device and assembled into a catheter delivery system for delivery intraluminally or. directly implanted.

In all four examples. the prosthesis may be of a straight. bifurcated or otherwise designed configuration.

Thus. while there have been described what are presently believed to be the preferred embodiments of the invention. those skilled in the art will realize that various changes and modifications may be made to the invention without departing from the spirit of the invention. and it is intended to claim all such changes and modifications which fall within the scope of the invention.

What is claimed is:

1. A method for intraluminally repairing a damaged lumen in a patient comprising:

delivering an expandable prosthesis to a site of damage in said lumen. said prosthesis being formed from a tubular substantially fluid-impermeable polymeric fabric having yams which extend around the circumference of said fabric and which are sufficiently undrawn to allow for controlled inelastic radial expansion upon the application of a preselected radial force thereto: and

delivering an internal preselected radial force to said prosthesis sufficient to inelastically expand said prosthesis.

2. The method of claim **1**. wherein said prosthesis is expanded via a balloon catheter.

3. The method of claim **1**. wherein said prosthesis includes means for securing said prosthesis to said lumen.

4. The method of claim **3**. further comprising the step of securing said expandable prosthesis to said lumen.

5. The method of claim **1**. wherein said lumen is a blood vessel.

6. The method according to claim **1**. wherein said prosthesis is delivered intraluminally to said damaged lumen via a catheter.

7. The method of claim **6**. wherein said prosthesis is initially sized for intraluminal delivery via said catheter without need for rolling or bunching of said prosthesis.

8. The method according to claim **6**. wherein said prosthesis is expanded until its diameter substantially conforms to that of said damaged lumen.

9. The method according to claim **1**. wherein said patient is a child. and said prosthesis is surgically implanted in said child.

10. The method according to claim **9**. wherein said prosthesis is expanded following a period of growth in said child until its diameter substantially conforms to that of a connecting host lumen which has experienced a period of circumferential growth.

* * * * *

WHAT IS CLAIMED IS:

11. A method for intraluminally repairing a damaged lumen in a patient comprising:

delivering an expandable prosthesis to a site of damage in said lumen, said prosthesis formed from a tubular polymeric fabric and being a radially expandable tubular prosthesis which allows controlled inelastic radial expansion; and

delivering an internal preselected radial force to said prosthesis sufficient to inelastically expand said prosthesis.

12. The method of claim 11 wherein said expandable prosthesis further includes an expandable stent circumferentially disposed interiorly or exteriorly of said prosthesis.

13. The method according to claim 11 wherein said prosthesis is expanded via a balloon catheter.

14. The method of claim 11 wherein said prosthesis includes means for securing said prosthesis to said lumen.

15. The method of claim 14 further comprising the step of securing said expandable prosthesis to said lumen.

16. The method of claim 11 wherein said lumen is a blood vessel.

17. The method according to claim 11 wherein said prosthesis is delivered intraluminally to said damaged lumen via a catheter.

18. The method of claim 17 wherein said prosthesis is initially sized for intraluminal delivery via said catheter without need for rolling or bunching of said prosthesis.

19. The method according to claim 17 wherein said prosthesis is expanded until its diameter substantially conforms to that of said damaged lumen.

20. The method according to claim 11, wherein said patient is a child, and said prosthesis is surgically implanted in said child.

21. The method according to claim 20 wherein said prosthesis is expanded following a period of growth in said child until its diameter substantially conforms to that of a connecting host lumen which has experienced a period of circumferential growth.

22. A method of making a tubular expandable prosthesis comprising:

weaving two polymeric yarns together to form a tube; and

attaching an expandable stent circumferentially to said tube.

23. A method according to claim 22 wherein said stent is attached to an interior surface of said tube.

24. A method according to claim 22 wherein said stent is attached to an exterior surface of said tube.

25. A method of making a tubular expandable prosthesis comprising:

braiding three polymeric yarns together to form a tube; and

attaching an expandable stent circumferentially to said tube.

26. A method according to claim 25 wherein said stent is attached to an interior surface of said tube.

27. A method according to claim 25 wherein said stent is attached to an exterior surface of said tube.

28. A radially expandable prosthesis produced by the process of:

weaving two polymeric yarns together to form a tubular structure; and

attaching an expandable stent circumferentially to said tubular structure.

29. A radially expandable prosthesis produced by the process of:

braiding three polymeric yarns together to form a tubular structure; and

attaching an expandable stent circumferentially to said tubular structure.

30. An expandable tubular prosthesis used for intraluminally repairing a damaged lumen in a patient, said prosthesis formed from a tubular polymeric fabric and being a radially expandable tubular prosthesis which allows controlled inelastic radial expansion.

31. The prosthesis according to claim 30 wherein said prosthesis includes an expandable stent circumferentially disposed interiorly or exteriorly of said prosthesis.

[57] **ABSTRACT**

A radially expandable tubular prosthesis which allows for controlled expansion in a circumferential direction following implantation while limiting expansion in a longitudinal direction. The prosthesis is particularly suited to intraluminal implantation via a catheter and is also particularly suited for percutaneous implantation in children.

10 Claims, 5 Drawing Sheets

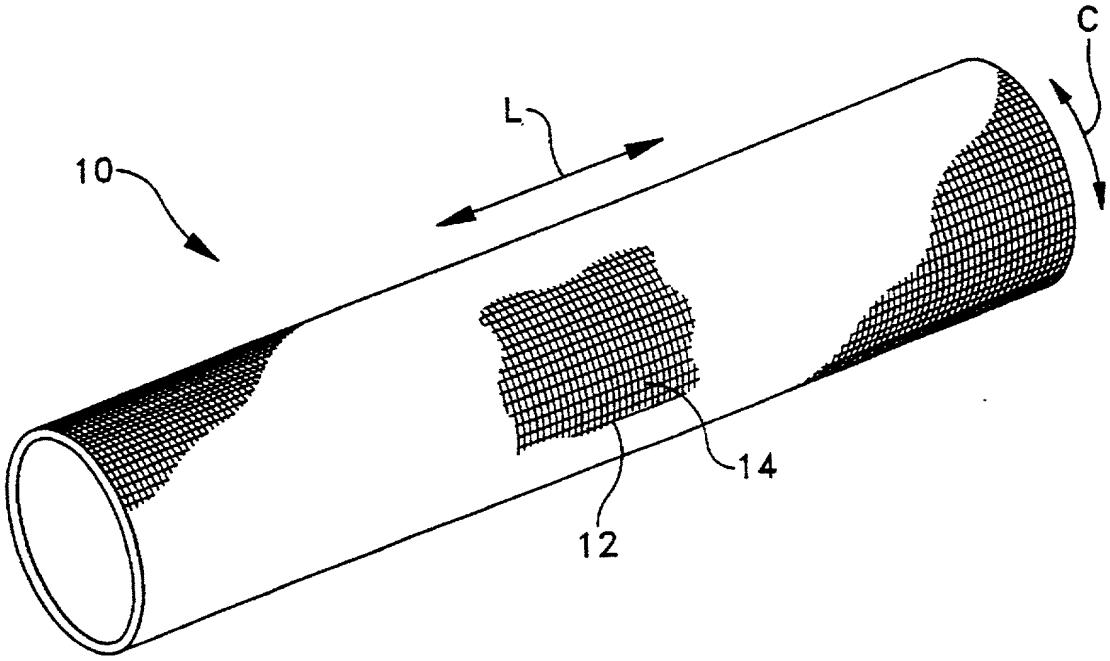
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FIG-1

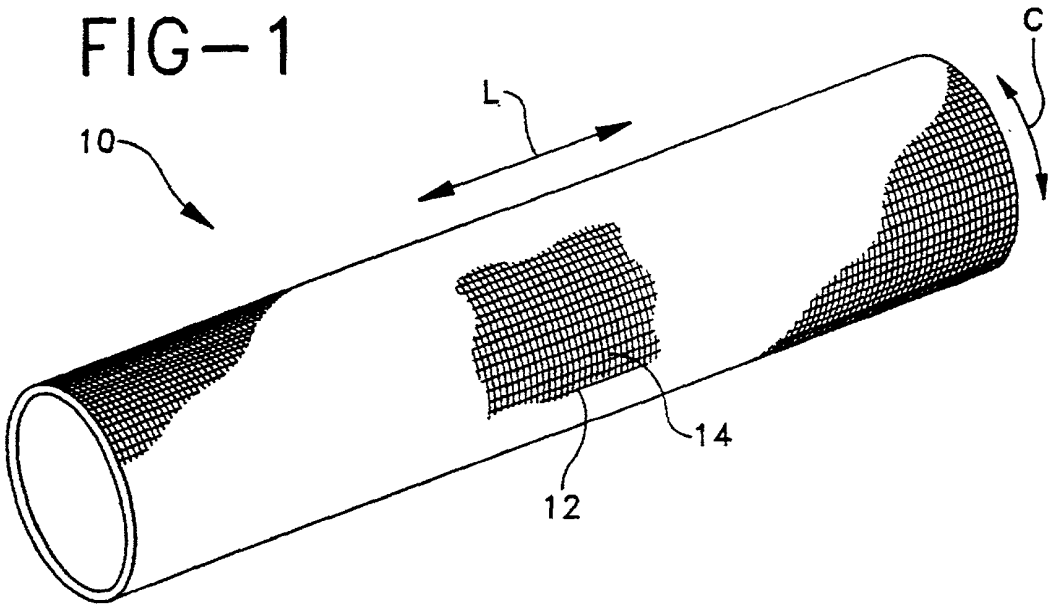


FIG-2

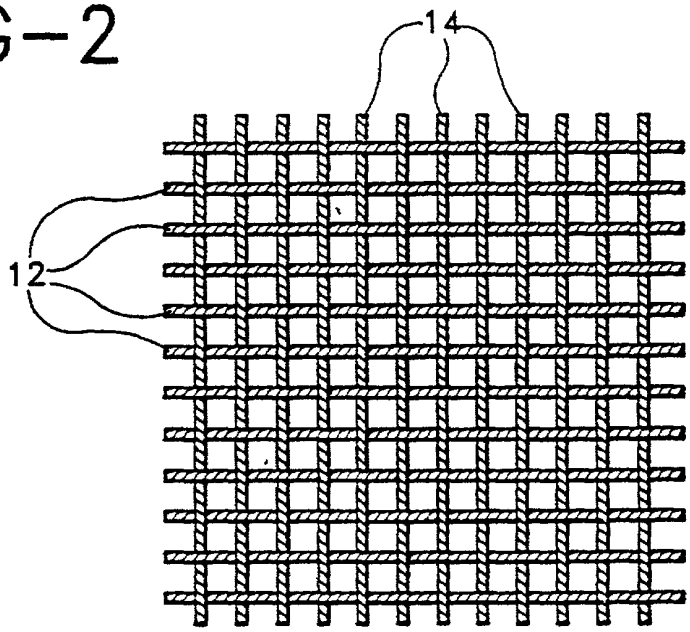
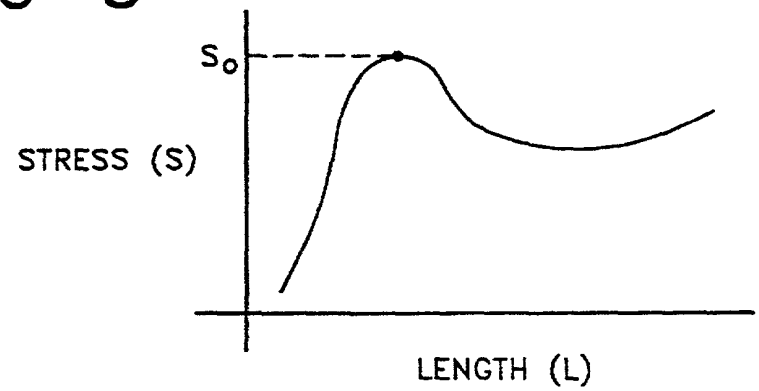


FIG-3



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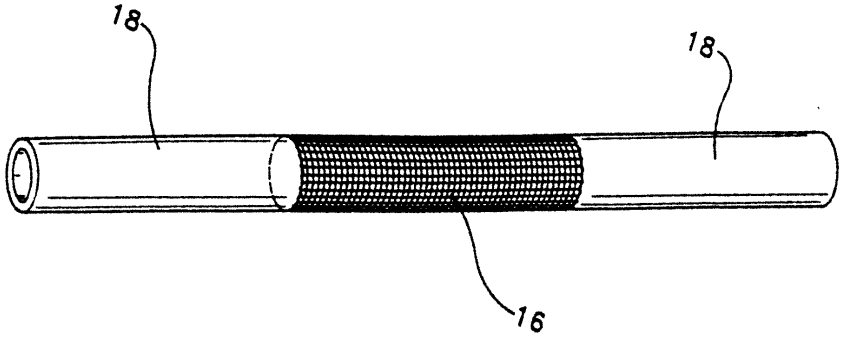

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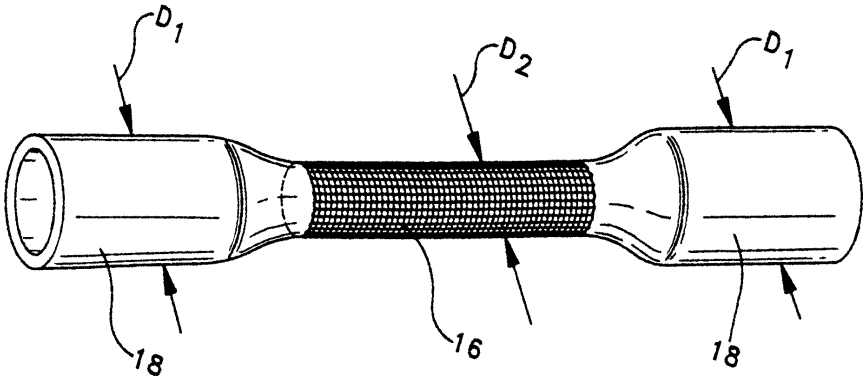


FIG-6

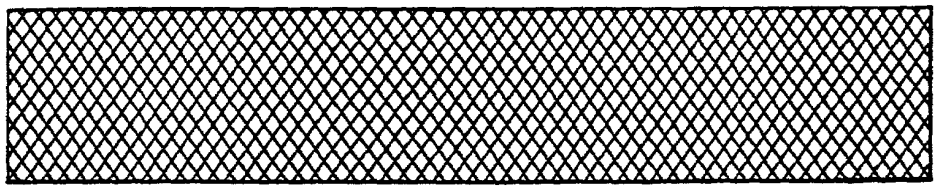
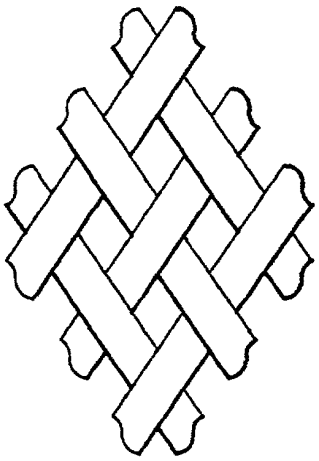


FIG-6a



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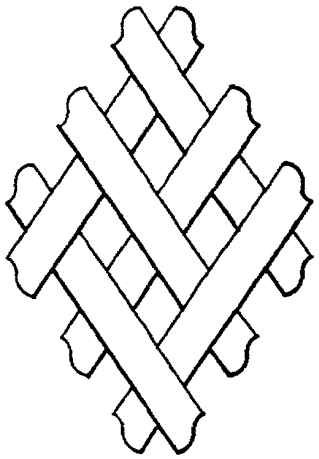
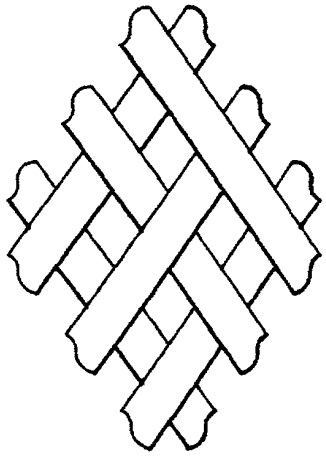


FIG-6c



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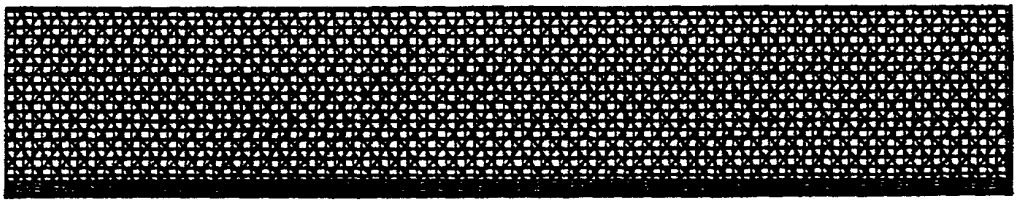


FIG-7a

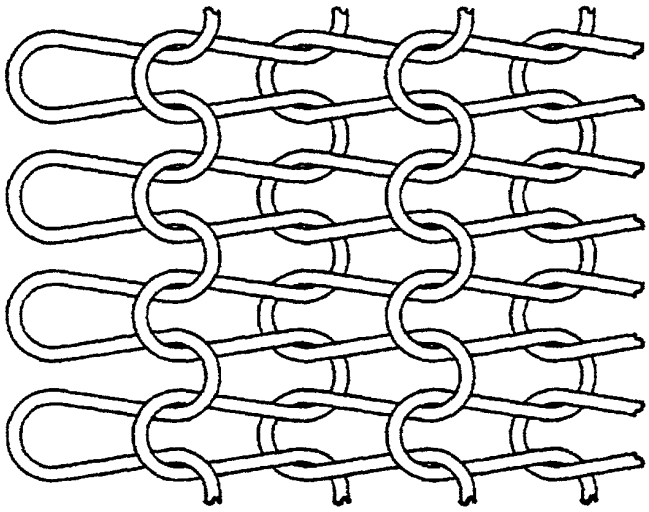


FIG-8

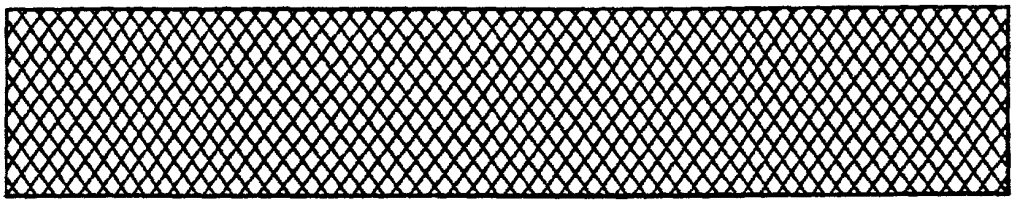
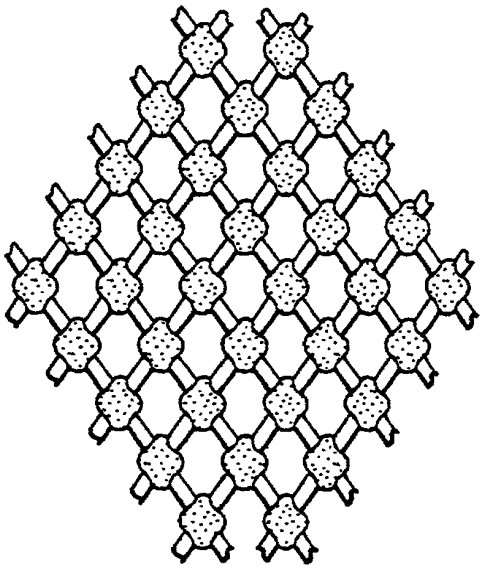


FIG-8a



Practitioner's Docket No. 498-18 DIV/RES **PATENT**

REISSUE APPLICATION DECLARATION AND POWER OF ATTORNEY (BY INVENTOR(S) OR ASSIGNEE)

(complete A or B)

A. ☒ DECLARATION BY THE INVENTOR(S)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, I believe I am the original, first and sole inventor *(if only one name is listed below)* or an original, first and joint inventor *(if plural names are listed below)* of the subject matter that is described and claimed in letters patent number 5,653,746, granted on August 5, 1997, and for which invention I solicit a reissue patent on the invention entitled Radially Expandable Tubular Prosthesis

the specification of which

☒ is attached hereto.

☐ was filed on _____, as reissue application number / and was amended on _____ *(if applicable).*

☐ I hereby declare that there is no assignee for this application.

NOTE: "Where no assignee exists, applicant should affirmatively state that fact. If the file record is silent as to the existence of an assignee, it will be presumed that no assignee exists." M.P.E.P., 6th ed., rev. 1, § 1410.01.

B. ☐ DECLARATION BY ASSIGNEE

NOTE: The assignee of the entire interest may make the declaration, if the reissue application does not seek to enlarge the scope of the claims of the original patent. 37 C.F.R. § 1.172.

_____, _____,
(type or print name of declarant) Title

of _____,
Name of company or legal entity on whose behalf declarant is authorized to sign

declare that I am a citizen of _____ and resident of _____,

_____, that the entire title to letters patent number _____,

for _____,

granted on _____, 19____ to _____
Inventor(s)

is vested in _____
Name of company or legal entity

that I believe said named inventor(s) to be an original, first and sole inventor *(if only one name is listed)* or an original, first and part inventor *(if plural names are listed)* of the subject matter that is described and claimed in the aforesaid letters patent and in the foregoing specification and for which invention I solicit a reissue patent.

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR
(37 C.F.R. § 1.175)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

☒ I acknowledge the duty to disclose information that is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

In compliance with this duty, there is attached an information disclosure statement in accordance with 37 C.F.R. § 1.98.

PRIORITY CLAIM

NOTE: A "claim" for the benefit of an earlier filing date in a foreign country under 35 U.S.C. 119(a)-(d) must be made in a reissue application even though such a claim was made in the application on which the original was granted. However, no additional certified copy of the foreign application is necessary. M.P.E.P., 6th ed., rev. 1, § 1417.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

(complete C or D)

C. ☒ No such applications have been filed.

D. ☐ Such applications have been filed as follows:

EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO SAID APPLICATION

Country	Application No.	Date of filing (day, month, year)	Date of issue (day, month, year)	Priority Claimed
				☐ YES NO ☐
				☐ YES NO ☐
				☐ YES NO ☐

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO SAID APPLICATION

BENEFIT OF PROVISIONAL APPLICATION

STATEMENT OF INOPERATIVENESS OR INVALIDITY OF ORIGINAL PATENT

(37 C.F.R. § 1.175)

That I believe the original patent to be

☒ partly

☐ wholly

inoperative or invalid by reason of (37 C.F.R. § 1.175(a)(1)):

(check all items that may apply)

☐ a defective specification

☐ a defective drawing

☒ the patentee claiming more or less than the patentee had a right to claim in the patent.

NOTE: At least one error must be relied upon as the basis for the reissue. 37 C.F.R. § 1.175(a)(1).

That the error listed above, which are being corrected, up to the time of the filing of this reissue declaration arose without any deceptive intention on the part of the applicant. (37 C.F.R. § 1.175(a)(2).

NOTE: For any error corrected not covered by this declaration applicant must submit, before allowance, a supplemental declaration stating that every such error arose without any deceptive intention on the part of the applicant. 37 C.F.R. § 1.175(b)(1).

☐ Corroborating affidavits or declarations of others accompany this declaration.

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith

Charles R. Hoffmann, Reg. No. 24,102; Ronald J. Baron, Reg. No. 29,281; Gerald T. Bodner, Reg. No. 30,449; Alan M. Sack, Reg. No. 31,874; A. Thomas Kammer, Reg. No. 28,226; R. Glenn Schroeder, Reg. No. 34,720; Glenn T. Henneberger, Reg. No. 36,074; Jessica H. Tran, Reg. No. 40,842; Irving N. Feit, Reg. No. 28,601; Anthony E. Bennett, Reg. No. 40,910; Gregory A. Bachmann, Reg. No. P41,593; Steven T. Zuschlag, Reg. No. 43,309, Susan A. Sipos, Reg. No. 43,128; William D. Schmidt, Reg. No. 39,492; and Kevin E. McDermott, Reg. No. 35,946, each of them of HOFFMANN & BARON, LLP, 6900 Jericho Turnpike, Syosset, New York 11791; and Daniel A. Scola, Jr., Reg. No. 29,855; Salvatore J. Abbruzzese, Reg. No. 30,152; Kirk M. Miles, Reg. No. 37,891; Robert F. Chisholm, Reg. No. 39,939; Kellyanne Merkel, Reg. No. 43,800; Nancy A. Bird, Reg. No. 28,398; John S. Sopko, Reg. No. 41,321; and Barry H. Jacobsen, Reg. No. 43,689, each of them of HOFFMANN & BARON, LLP, 1055 Parsippany Boulevard, Parsippany, New Jersey 07054.

☐ I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

☐ Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO

☒ Address
Hoffmann & Baron, LLP
6900 Jericho Turnpike
Syosset, New York 11791

☐ Customer Number _____

DIRECT TELEPHONE CALLS TO:
(Name and telephone number)

Daniel A. Scola, Jr.

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signature(s)

☒ **BY THE INVENTOR(S)**

Full name of sole or first inventor Peter J. Schmitt

Inventor's signature _____

Date _____ Country of Citizenship U.S.

Residence 41 Bubenko Drive, Garnerville, NY 10923

Post Office Address same as above

Full name of second joint inventor, if any _____

Inventor's signature _____

Date _____ Country of Citizenship _____

Residence _____

Post Office Address _____

☐ **BY ASSIGNEE OR PERSON AUTHORIZED TO SIGN ON BEHALF OF ASSIGNEE**

NOTE: Even though inventor(s) do not sign, complete above information for inventor(s).

(complete the following, if applicable)

_____
(type name of assignee)

_____
Address of assignee

_____

_____
Title of person authorized to sign on behalf of assignee

☐ Assignment recorded in PTO on _____

Reel _____

Frame _____

☐ A separate ☐ "ASSIGNMENT (DOCUMENT) COVER SHEET" or ☐ FORM PTO 1595 is submitted herewith along with the assignment _____

STATEMENT BY ASSIGNEE

☒ Attached is a "STATEMENT UNDER 37 C.F.R. 3.73(b)," establishing the right of the assignee to take action in this reissue.

_____

Signature of assignee or person authorized to sign on behalf of assignee

(check proper box(es) for any added page(s) forming a part of this declaration)

☐ Signature for third and subsequent joint inventors. Number of pages added. _____.

☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. Number of pages added. _____.

☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 C.F.R. § 1.47. Number of pages added. _____.

☐ Statement of inoperativeness or invalidity of original patent. 37 C.F.R. § 1.175. Number of pages added _____.

☐ Authorization of attorney(s) to accept and follow instructions from representative.

☐ Corroborating statements of others.